

U.S. Application No. 09/853,581
Amendment dated February 28, 2005
In reply to the final office action of December 14, 2004
Attorney Ref. No.: 037003 - 0280617

NOT Entered
GN 3/13/05

I. AMENDMENT

Amendments to the Claims

This listing of claims will replace all prior versions, and listings, of claims in the application:

Claims 44, 48, 52, 53, 57, and 62-64 are amended, and claim 47 is canceled.

1-43. (Canceled)

44. (Currently amended) A method of treating cancer comprising administering to a patient in need thereof:

(a) an admixture comprising a cancer or tumor antigen expressed by cells of the cancer to be treated and a microfluidized antigen formulation comprising:

- (i) a stabilizing detergent,
- (ii) a micelle-forming agent, and
- (iii) a biodegradable and biocompatible oil,

said antigen formulation being formulated as a stable oil-in-water emulsion;

wherein said admixture is administered to said patient in an amount sufficient to induce a cytotoxic T-lymphocyte response in said patient which is specific for the cancer or tumor antigen contained in said admixture, and

(b) a therapeutically effective amount of at least one agent which is capable of neutralizing, blocking, antagonizing, or down regulating the activity or preventing activation of transforming growth factor β (TGF β) specifically, which agent is selected from the group consisting of an anti-TGF β antibody, a TGF β R-fusion protein, a TGF β analog, a TGF β binding protein, and a TGF β R blocking antibody;

wherein the antigen-containing admixture and the at least one agent which is capable of neutralizing, blocking, antagonizing, or down regulating the activity or preventing activation of TGF β are administered sequentially or concurrently, and in any order.